EXHIBIT 20

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October 20, 2023

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Re: *Arbutus Biopharma Corporation et al. v. Moderna, Inc. et al.*, C.A. No. 22-252-MSG (D. Del.) – **Samples**

Counsel:

We write regarding the parties' September 28, 2023 meet-and-confer and Plaintiffs' October 6, 2023 letter.

We understand that Plaintiffs' current proposal is as follows: Plaintiffs seek samples of drug product vials containing the equivalent of 100 mg lipid content from each of 50 finished drug batches that Plaintiffs' will select across the mRNA-1273 LNP part numbers identified by Moderna.

Thank you for agreeing to meet and confer again on Monday, October 23.

1. Drug Product Samples

Plaintiffs' persist in ignoring important, undisputed facts in their continued request for an extreme and unreasonable volume of samples.

First, this is not a situation where testing and related documentation does not already exist. Plaintiffs continue to ignore that Moderna has already produced data concerning the lipid content of its product generally and each batch individually, and has committed to further producing additional testing data kept in the ordinary course regarding the lipid content of each batch. The fact that Plaintiffs appear to just not like the results of such testing does not automatically make the production of large amounts of samples necessary or proportionate with respect to resolution of the issues in this case.

Second, even considering the very large volume of documents and data that has already been or will be produced with respect to lipid content, Moderna has nevertheless offered to take a step-wise approach to production of samples, beginning with production of 3 drug product samples from one batch of each part number, so that Plaintiffs may receive additional samples sooner,[1] wherein Plaintiffs could come back to Moderna in the event that, when they complete tests on those batches, they determine that further batches are necessary. Plaintiffs rejected Moderna's offer. As we have previously stated, Moderna is actively working on producing up to 3 drug product vials from each part number (if available). Moderna would also retain 3 corresponding samples for purposes of this litigation. Moderna has been attempting to work with Plaintiffs in trying to reach a reasonable compromise, yet Plaintiffs have persisted with their extremely high-volume requests.

(a) Plaintiffs Seek an Unreasonable Number of Samples from 50 batches

With regard to the number of samples, as we pointed out on the meet-and-confer, Plaintiffs' comparison of the number of samples they request to Moderna's manufacturing capacity is entirely irrelevant. *See, e.g.*, Sheh Oct. 6, 2023 letter at 1 ("Plaintiffs disagree that it is reasonable for Moderna to limit its sample production to 39 vials from 13 batches where millions of vials have been manufactured and sold across approximately a thousand batches"); *id.* at 2 ("a tiny fraction of the total number of batches and material that Moderna has manufactured to date"). Proportionality is not based on how much product Moderna makes and how many batches, but what quantity of samples Plaintiffs need to prove their case. What Plaintiffs refer to as a "tiny fraction" amounts to ***production of thousands of doses***, an amount Plaintiffs are highly unlikely to test during the course of this litigation.

(b) Plaintiffs Seek Unreasonable Amounts of Samples (vials equivalent to 100 mg lipid content) Per Batch

With regard to the amount of each sample, for months we have asked Plaintiffs why they need vials equivalent to 100 mg of lipid per batch and not once have Plaintiffs provided an answer. Your October 6 letter once again evades the question. In fact, your only acknowledgment of this query is followed by: "we have made clear that the requested quantities are needed for testing and in light of Moderna's position that it may dispute infringement on a batch-by-batch basis." Sheh Oct. 6, 2023 letter at 3. This provides no clarity to Moderna as to why Plaintiffs demand such large amounts of Moderna's product. As we have stated, Moderna is not aware of any testing that would require such large amounts of material. Plaintiffs likewise confirmed during the meet-and-confer that they would not provide any justification for the amount of sample they seek, claiming these discussions are not "a vehicle for Moderna to get insight into work product or expert testing." [redacted]

[1] We note that Plaintiffs previously agreed to Moderna's production of 3 vials from a single batch of drug product and Moderna made such production back in April 2023.

It also appears that Plaintiffs are taking the position that they cannot determine lipid content of the drug product as it exists in the ordinary course (i.e., as sold) by Moderna,[2] and instead are seeking these samples with the intent to somehow combine samples to amass 100 mg of lipid. Plaintiffs have been entirely unwilling to compromise—maintaining their request for vials equivalent 100 mg of lipid per batch since serving the RFP in December 2022. Further, despite months of meeting and conferring, Plaintiffs informed Moderna for the first time during the September 28, 2023 meet-and-confer that they refused to reduce the amount of samples they were seeking.

With respect to your questions regarding Moderna's regulatory retained samples of drug product, Moderna's standard operating procedure is compliant with FDA's regulation under 21 CFR 211-170, which requires a reserved sample that is representative of each lot in each shipment be retained, and that the quantity of the reserved sample be two times the quantity sufficient to perform all the required tests (except for sterility and pyrogens). [redacted]

For the purposes of this litigation, Moderna expects to be able to produce up to three vials of drug product across drug product lots that have expired. As described above and in our September 19, 2023 letter, Moderna would produce those 3 vials from one batch of each of the different part numbers. Consistent with Moderna's earlier sample production, Moderna would retain 3 corresponding samples for purposes of this litigation. With respect to expired drug product, Moderna would produce samples with the understanding that the expired materials may not exhibit the same lot characteristics demonstrated at the time of initial release. In the absence of any justification from Plaintiffs as to why 100 mg of lipid content per batch is needed, Moderna's proposal is reasonable and proportional to the needs of the case.

Finally, with regard to recently manufactured batches, as we previously explained, Moderna is currently working to rapidly distribute Moderna's updated booster product for this fall season. Plaintiffs' requests for large amounts of samples (equivalent to 100 mg of lipid per batch) are unnecessary for the reasons mentioned above, as well as burdensome to the extent Plaintiffs seek a significant diversion of product from the market and doses for patient use.

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2 [redacted]

(c) Plaintiffs' Request is Overly Burdensome and Not Proportional

Regarding burden as we have already explained to Plaintiffs, identification of the number of samples remaining in a given batch across more than one thousand batches will be a manual exercise of not only checking electronic systems for said availability, but confirming inventory in Moderna's freezers, which will be a laborious and time-consuming process that will not only expend the time of Moderna's employees who will be doing this on top of their regular roles and responsibilities at the company but will also put other samples at risk of being exposed to higher temperatures. Given the burden Moderna cannot perform this inventory exercise until the parties have settled on what will need to be produced. In addition to identifying what is available, extensive paperwork will be needed to justify the deviation of production of regulatory retains. This too is not a quick procedure.

For all the reasons discussed above, at least the request for 100 mg of lipid per batch is entirely unreasonable, particularly where Plaintiffs have never provided a reason why such an enormous quantity is needed. Additionally, Moderna has described at least a portion of the costs associated with the production of the requested samples above. Moderna cannot quantify the costs and expenses given that the parties have reached no agreement on the quantity of samples to be produced. Moderna understands that Plaintiffs are refusing to confirm they will cover the costs at this time.

(d) Plaintiffs' Proposal on "Representativeness"

With regard to representativeness, Plaintiffs' proposed "selection" process likewise fails to pass muster. First, Plaintiffs' proposal continues to ignore the testing results and data Moderna has already produced or has agreed to produce. Second, Plaintiffs intend to cherry-pick the batches to be produced, but then argue that those hand-selected batches should be representative of all material within the same part number. As we noted on the meet-and-confer, hand-selecting the ones Plaintiffs wish Moderna to produce is entirely inconsistent with the batches being considered representative. Plaintiffs refused to state during the meet-and-confer what criteria they would use to make such a selection, further hampering Moderna's ability to try to reach a common ground on this issue. Plaintiffs' letter is also unclear as to how representativeness would apply in practice. For example, if Plaintiffs demand samples from 10 batches for one part number, it would be unreasonable to suggest that Plaintiffs could offer evidence of a single test or a single sample while withholding others and have that one test result supersede all others. Regardless, please provide a draft stipulation that lays out Plaintiffs' proposal in more detail so that we may consider your position.

2. <u>RFPs 110 and 111</u>

[redacted]

[redacted]

Furthermore, Plaintiffs' attempt to shoehorn their unfounded theory—about "samples," of a mid-manufacturing process, which do not exist in the ordinary course—into the allegations in their Complaint, mischaracterizes the Complaint. Specifically, Plaintiffs argue that "[s]uch samples plainly relate to Plaintiffs' claims that Moderna has infringed through manufacturing the Accused Product incorporating Arbutus's patent LNP technology, and by selling, importing, and inducing others to make and use a product that embodies a component of a patented manufacture, combination or composition." Sheh Oct. 6, 2023 letter at 3. But that is not what the Complaint says; the Complaint only alleges infringement "under 35 U.S.C. § 271(a) by manufacturing, offering to sell, selling, or using within the United States, or importing into the United States, ***the Accused Product***." *See, e.g.*, D.I. 1, ¶¶70, 89, 108, 130, 154, 173. Regardless, as explained in our September 19, 2023 letter and again on our most recent meet-and-confer, Moderna does not have anything to produce in response to Plaintiffs' request for samples of this mid-process material which is not available in the ordinary course. We understand these RFPs to be resolved.

3. [redacted] Product Samples

Regarding samples of [redacted], Plaintiffs have not articulated any claim or defense to which such samples would be relevant. [redacted] Moderna will respond to the newly served RFP in due course.

Sincerely,

/s/Mark C. McLennan
Mark C. McLennan

cc: Counsel of Record